AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

1. (Currently Amended) A pharmaceutical formulation ~~containing~~ comprising:
(1) THAM [tris(hydroxymethyl) aminomethane] as a selective absorbefacient to enhance through the nasal ~~mucas-lined-epithelium~~ mucosa-lined-epithelium the absorption of substances of peptide nature; and
(2) a therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment;
in a pharmaceutically acceptable, aqueous liquid diluent or carrier, said formulation being in a form suitable for nasal administration.

2. (Currently Amended) The pharmaceutical formulation, according to claim 1, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of peptide hormones ~~or~~ and hormone derivatives, physiologically active lymphokines ~~or~~ and monokines, peptidic enzymes, proteic vaccines, peptidic toxoids, and ~~personalised~~ personalized proteins derived from genoma, ~~which can be conveniently used~~ in a form suitable for nasal administration.

3. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic

fragment is selected from the group ~~of~~ consisting of the peptide hormones ~~or~~ and hormone derivatives ~~such as~~ buserelin, desmopressin, vasopressin, angiotensin, felypressin, octreotide, somatropin, thyrotropin (TSH), somatostatin, gosereline, thryptorelin and insulin (~~from~~ selected from the group consisting of caw and pig, ~~or~~ synthetic ~~or~~, and recombinant).

4. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of the peptide hormones ~~or~~ and hormone derivatives ~~such as~~ protirelin, adrenocorticotropin (ACTH), prolactin, luteinizing hormone (LH), luteinizing hormone-release hormone (LH-RH), leuprorelin, calcitonin (selected from the group consisting of human, chicken, eel, porcine ~~or~~ and recombinant), carbocalcitonin and calcitonin gene related peptides (CGRP).

5. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of the peptide hormones ~~or~~ and hormone derivatives ~~such as~~ kallikrein, parathyrin, glucagon, oxytocin, gastrin, secretin, leptin, nafarelin, serum gonadotropin, gonadotropin release factor, growth hormone, erytropoietin, hirudin, urograstrone, renin and human parathyroid hormone (h-PTH).

6. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of the physiologically active

lymphokines ~~or~~ and monokines ~~such as~~ interferon, interleukin, transferrin, histaglobulin, macrocortine, endorphins, enkephalins and neurotensin.

7. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of the peptidic enzymes ~~such as~~ lysozyme, urokinase and superoxide dismutase.

8. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of the proteic vaccines ~~as~~ acellular and cellular pertussis, diphtheria, tetanus and influenza vaccines.

9. (Currently Amended) The pharmaceutical formulation, according to claim 1 ~~or~~ ~~2~~, wherein the nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is selected from the group ~~of~~ consisting of the peptidic toxoids ~~such as~~ diphtheria, and tetanus and ~~from~~ the ~~group of personalised~~ personalized proteins derived from genoma.

10. (Currently Amended) The pharmaceutical formulation, according to ~~any one of the preceding claims~~ claim 1, wherein (1) the therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is in ~~concentrations~~ a concentration of 0.001 microgram/ml to 50.0 mg/ml or of 10 Units/ml to 20000 Units/ml, in relation to the therapeutically effective dose ~~to be~~

~~administered by~~ for administration by the endonasal route; and (2) THAM is in ~~concentrations~~ a combination of 0.5 mg/ml to 30.0 mg/ml.

11. (Currently Amended) The pharmaceutical formulation, according to ~~any one of the preceding claims~~ claim 1, wherein (1) the therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is in ~~concentrations~~ a concentration of 0.01 microgram/ml to 50.0 mg/ml or of 20 Units/ml to 12500 Units/ml; and (2) THAM is in ~~concentrations~~ a concentration of 2.0 mg/ml to 10.0 mg/ml.

12. (Currently Amended) The pharmaceutical formulation, according to ~~any one of the preceding claims~~ claim 1, wherein (1) the therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment is in ~~concentrations~~ a concentration of 0.05 microgram/ml to 10.0 mg/ml or of 100 Units/ml to 6000 Units/ml; and (2) THAM is in ~~concentrations~~ a concentration of 2.5 mg/ml to 4.5 mg/ml.

13. (Currently Amended) The pharmaceutical formulation, according to ~~any one of the preceding claims~~ claim 1, wherein said pharmaceutical formulation is in the form of ready-to-use or of reconstituted solution suitable for nasal administration in the form of a drop type or of a nasal spray.

14. (Currently Amended) The pharmaceutical formulation, according to ~~any one of the preceding claims, suitably administrable~~ claim 1, for administration in a

metered single dose volume or in multiple doses thereof, ~~said~~ each actuation comprising a metered dose volume between 50 microliters and 200 microliters.

15. (Currently Amended) A method for producing a pharmaceutical formulation according to ~~any one of the preceding claims~~ claim 1, wherein the aqueous liquid diluent or carrier comprises ~~optionally other~~ the pharmaceutically acceptable auxiliary ~~additives such as~~ additive (a) hydrochloric or citric acid; (b) one or a mixture of methyl or/and propyl p-hydroxybenzoate; ~~and~~ and/or (c) cysteine.

16. (Currently Amended) The method according to claim 15, wherein the pharmaceutically acceptable, aqueous liquid diluent or carrier further comprises ~~optionally other~~ the pharmaceutically acceptable ~~auxiliary additives such as~~ additive (a) hydrochloric acid 0.1 N in ~~concentrations~~ a concentration of 0.3 mg/ml to 50.0 mg/ml or citric acid in ~~concentrations~~ a concentration of 0.6 mg/ml to 60.0 mg/ml~~,~~ ~~more preferably of 2.8 mg/ml to 6.2 mg/ml~~; (b) one or a mixture of methyl or/and propyl p-hydroxybenzoate in ~~concentrations~~ a concentration not exceeding 0.3 mg/ml with a ratio of 2:1 to 20:1; and (c) cysteine in ~~concentrations~~ a concentration of 0.5 mg/ml to 10.0 mg/ml.

17. (Currently Amended) A method for producing a pharmaceutical formulation for nasal administration according to ~~any one of claims 1 to 14~~ claim 1, in the form of a ready-to-use solution, said method comprising the steps of: adding an adequate amount of distilled water to THAM, and optionally to methyl or/and propyl p-hydroxybenzoate, hydrochloric or citric acid and cysteine until complete dissolution;

and then dissolving at the end the adequate quantity of nasal peptide or its pharmaceutically acceptable salt or its peptidic fragment in ~~said~~ the solution mixture.

18. (Currently Amended) The method according to claim 17, which further ~~includes~~ comprises the step of: filtering to make the solution suitable for nasal administration and filling a mono-disposable, or multidose device system with the filtrate, more preferably with a progressive dose counting system.

19. (Currently Amended) A method for producing a pharmaceutical formulation for nasal administration, according to ~~any one of claims 1 to 14~~ claim 1, in the form of reconstituted solution, said method comprising:

preparing container ~~n.° 1~~ no. 1 with the nasal peptide either by dosing in the container the corresponding weight of powder of active nasal peptide or by preparing a suitable solution with a known concentration of the same, pouring the individually dosed volume into the container and then lyophilizing it to yield a lyophilized powder;

preparing container ~~n.° 2~~ no. 2 comprising the solvent mixture for reconstitution, resulting from adding an adequate amount of distilled water to THAM, and optionally to methyl or/and propyl p-hydroxybenzoate, hydrochloric or citric acid and cysteine until complete dissolution;

filtering to make the solution suitable for nasal administration; and

filling container ~~n.° 2~~ no. 2 with the filtrate.

20. (Currently Amended) The method according to claim 19, wherein container ~~no .° 1~~ no. 1 is prepared by dosing directly in the container the corresponding weight of active nasal peptide powder ~~le)~~, or by preparing a suitable solution with a known concentration of the same, pouring the individually dosed volume directly into the container and then lyophilizing it directly in the container to yield a lyophilized powder.

21. (Currently Amended) The method according to claim 19 ~~or 20~~, which further ~~includes~~ comprises the step of: preparing the reconstituted solution at the time of starting its use by pouring the solvent mixture of container ~~n.° 2~~ no. 2 into container ~~n. ° 1;~~ no. 1; mixing thoroughly by rotation until complete dissolution; and screwing the multidose device system on the neck of container ~~n. 1~~ no. 1, comprising the reconstituted solution.

22. (Currently Amended) The pharmaceutical formulation, according to ~~any one of claims 1 to 14, which have~~ claim 1, having a long shelf life, and when ~~in use, provide~~ in use providing compositions of a therapeutically effective amount of active nasal peptide, its pharmaceutically acceptable salt or its peptidic fragment.

23. (Currently Amended) A method for treating~~, with a pharmaceutical formulation according to any one of claims 1 to 14,~~ a patient which comprises intranasally administering in the form of drop type or of nasal spray to said patient, a dosed volume of ~~said~~ a formulation according to claim 1, ~~comprising a therapeutically effective amount of nasal peptide or of its pharmaceutically acceptable salt or peptidic fragment conveniently combined with THAM in a pharmaceutically~~

~~acceptable liquid, aqueous carrier or diluent, with the scope~~ to elicit the desired pharmacological effect.

24. (Currently Amended) The method[[,]] according to claim 23, in which the administrable dose volume of the pharmaceutical formulation, comprised in a metered monodose disposable or in a multidose system thereof, is comprised between 50 microliters and 200 microliters per actuation.

25. (New) The method according to claim 16, wherein (a) is citric acid in a concentration of 2.8 mg/ml to 6.2 mg/ml.